
HOUSE BILL No. 1569

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-7-2-20.2; IC 12-15-35.

Synopsis: Internet prescription drug information. Requires the drug utilization review board to develop and implement an Internet site to provide to the public comparative information concerning efficacy, use, and cost of prescription drugs.

Effective: July 1, 2003.

Kersey

January 16, 2003, read first time and referred to Committee on Technology, Research and Development.

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Introduced

First Regular Session 113th General Assembly (2003)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2002 Regular or Special Session of the General Assembly.

HOUSE BILL No. 1569

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

1 SECTION 1. IC 12-7-2-20.2 IS ADDED TO THE INDIANA CODE
2 AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
3 1, 2003]: **Sec. 20.2. "Average retail price" has the meaning set forth**
4 **in IC 12-8-15-1.**

5 SECTION 2. IC 12-7-2-190.6, AS ADDED BY P.L.107-2002,
6 SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
7 JULY 1, 2003]: Sec. 190.6. "Therapeutic classification" or "therapeutic
8 category", for purposes of IC 12-15-35 **and IC 12-8-15**, has the
9 meaning set forth in IC 12-15-35-17.5.

10 SECTION 3. IC 12-8-15 IS ADDED TO THE INDIANA CODE AS
11 A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY
12 1, 2003]:

13 **Chapter 15. Prescription Drug Information.**

14 **Sec. 1. As used in this chapter, "average retail price" means the**
15 **price charged for a prescription drug by a pharmacy to a**
16 **consumer without a third party payment source.**

17 **Sec. 2. The drug utilization review board established by**

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1 **IC 12-15-35-19 shall develop and implement an Internet site where**
 2 **information:**

3 **(1) presented in language and a format that is understandable**
 4 **to the general public; and**

5 **(2) comparing efficacy, use, and average retail price of**
 6 **prescription drugs within a therapeutic classification;**

7 **is available to the public.**

8 **Sec. 3. The therapeutics committee established by**
 9 **IC 12-15-35-20.5 shall develop a comparison of the prescription**
 10 **drugs available to the public within a therapeutic classification,**
 11 **including the:**

12 **(1) efficacy;**

13 **(2) purposes of use; and**

14 **(3) average retail price;**

15 **of each prescription drug for publication on the Internet site**
 16 **implemented under section 2 of this chapter.**

17 **SECTION 4. IC 12-15-35-28, AS AMENDED BY P.L.107-2002,**
 18 **SECTION 17, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE**
 19 **JULY 1, 2003]: Sec. 28. (a) The board has the following duties:**

20 **(1) The adoption of rules to carry out this chapter, in accordance**
 21 **with the provisions of IC 4-22-2 and subject to any office**
 22 **approval that is required by the federal Omnibus Budget**
 23 **Reconciliation Act of 1990 under Public Law 101-508 and its**
 24 **implementing regulations.**

25 **(2) The implementation of a Medicaid retrospective and**
 26 **prospective DUR program as outlined in this chapter, including**
 27 **the approval of software programs to be used by the pharmacist**
 28 **for prospective DUR and recommendations concerning the**
 29 **provisions of the contractual agreement between the state and any**
 30 **other entity that will be processing and reviewing Medicaid drug**
 31 **claims and profiles for the DUR program under this chapter.**

32 **(3) The development and application of the predetermined criteria**
 33 **and standards for appropriate prescribing to be used in**
 34 **retrospective and prospective DUR to ensure that such criteria**
 35 **and standards for appropriate prescribing are based on the**
 36 **compendia and developed with professional input with provisions**
 37 **for timely revisions and assessments as necessary.**

38 **(4) The development, selection, application, and assessment of**
 39 **interventions for physicians, pharmacists, and patients that are**
 40 **educational and not punitive in nature.**

41 **(5) The publication of an annual report that must be subject to**
 42 **public comment before issuance to the federal Department of**

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Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; and

(C) the primary care case management component of the

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children's health insurance program under IC 12-17.6;
in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(15) The duties specified in IC 12-8-15.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that is not included on the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be automatically required for a single source drug that is newly approved by the federal Food and Drug Administration and that is:

(1) in a therapeutic classification:

(A) that has not been reviewed by the board; and

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- 1 (B) for which prior authorization is not required; or
 2 (2) the sole drug in a new therapeutic classification that has not
 3 been reviewed by the board.
 4 (f) The board may not exclude a drug from the preferred drug list
 5 based solely on price.
 6 (g) The following requirements apply to a preferred drug list
 7 developed under subsection (a)(11):
 8 (1) The office or the board may require prior authorization for a
 9 drug that is included on the preferred drug list under the following
 10 circumstances:
 11 (A) To override a prospective drug utilization review alert.
 12 (B) To permit reimbursement for a medically necessary brand
 13 name drug that is subject to generic substitution under
 14 IC 16-42-22-10.
 15 (C) To prevent fraud, abuse, waste, overutilization, or
 16 inappropriate utilization.
 17 (D) To permit implementation of a disease management
 18 program.
 19 (E) To implement other initiatives permitted by state or federal
 20 law.
 21 (2) All drugs described in IC 12-15-35.5-3(b) must be included on
 22 the preferred drug list.
 23 (3) The office may add a new single source drug that has been
 24 approved by the federal Food and Drug Administration to the
 25 preferred drug list without prior approval from the board.
 26 (4) The board may add a new single source drug that has been
 27 approved by the federal Food and Drug Administration to the
 28 preferred drug list.
 29 (h) At least two (2) times each year, the board shall provide a report
 30 to the select joint commission on Medicaid oversight established by
 31 IC 2-5-26-3. The report must contain the following information:
 32 (1) The cost of administering the preferred drug list.
 33 (2) Any increase in Medicaid physician, laboratory, or hospital
 34 costs or in other state funded programs as a result of the preferred
 35 drug list.
 36 (3) The impact of the preferred drug list on the ability of a
 37 Medicaid recipient to obtain prescription drugs.
 38 (4) The number of times prior authorization was requested, and
 39 the number of times prior authorization was:
 40 (A) approved; and
 41 (B) disapproved.
 42 (i) The board shall provide the first report required under subsection

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(h) not later than six (6) months after the board submits an initial preferred drug list to the office.

SECTION 5. IC 12-15-35-28.5, AS ADDED BY P.L.107-2002, SECTION 18, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 28.5. The therapeutics committee established under section 20.5 of this chapter shall do the following:

(1) Advise and make recommendations to the board in the board's development and maintenance of a preferred drug list under section 28 of this chapter.

(2) Submit to the board a proposed preferred drug list that has been approved by a majority of a quorum of the therapeutics committee.

(3) Advise and make recommendations to the board in the board's review and maintenance of a preferred drug list.

(4) Perform the duties required under IC 12-8-15.

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